

## **HIGH ACTIVE FORMULA 75% HAND SANITIZER- alcohol liquid**

### **Paradigm Labs, Inc.**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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### **MPC High Active Formula 75% Hand Sanitizer**

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

### **Active Ingredient(s)**

Alcohol 75% v/v. Purpose: Antiseptic

### **Purpose**

Antiseptic, Hand Sanitizer

### **Use**

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

### **Warnings**

For external use only. Flammable. Keep away from heat or flame

### **Do not use**

- on children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

## Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

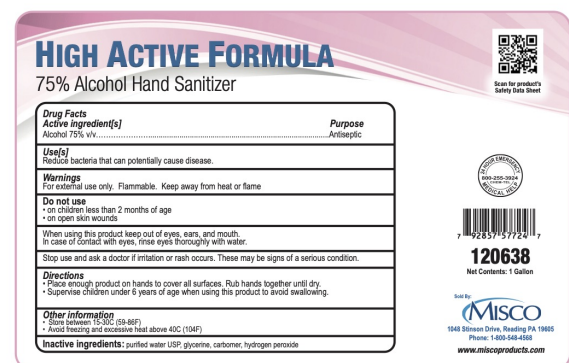
## Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

## Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

## Package Label - Principal Display Panel






Office Buildings  
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Healthcare  
De salud

Hospitals  
Hospitales

Restaurants  
Restaurantes

# High Active Formula

75% Alcohol Hand Sanitizer



High Active Formula  
75% Alcohol Hand Sanitizer

3785 mL NDC: 78918-101-02



Scan for product's Safety Data Sheet

## High Active Formula

75% Alcohol Hand Sanitizer

<b>Drug Facts</b>	<b>Purpose</b>
<b>Active ingredient(s)</b> Alcohol 75% v/v	Antiseptic
<b>Use(s)</b> Kills bacteria that can potentially cause disease.	
<b>Warnings</b> For external use only. Flammable. Keep away from heat or flame.	
<b>Do not use</b> • on children less than 2 months of age • on open skin wounds	
When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.	
<b>Directions</b> • Place enough product on hands to cover all surfaces. Rub hands together until dry. • Supervise children under 6 years of age when using this product to avoid swallowing.	
<b>Other information</b> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)	
<b>Inactive ingredients:</b> purified water USP, glycerine, carbomer, hydrogen peroxide	



120639  
Net Contents: 95 Gallons




1448 Shuman Drive, Reading, PA 19605  
Phone: 1-800-848-4359  
www.miscoproductions.com

## HIGH ACTIVE FORMULA 75% HAND SANITIZER

alcohol liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78918-101
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ALCOHOL</b> (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	2.15 mL in 100 mL
<b>HYDROGEN PEROXIDE</b> (UNII: BBX060AN9V)	0.351 mL in 100 mL
<b>WATER</b> (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78918-101-02	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/30/2020	
2	NDC:78918-101-01	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/30/2020	
3	NDC:78918-101-03	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/30/2020	
4	NDC:78918-101-04	208198 mL in 1 DRUM; Type 0: Not a Combination Product	09/30/2020	

5	NDC:78918-101-05	18927 mL in 1 PAIL; Type 0: Not a Combination Product	09/30/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part333A		09/30/2020	12/31/2023

**Labeler** - Paradigm Labs, Inc. (783327760)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Paradigm Labs, Inc		783327760	manufacture(78918-101)